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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/759,892	01/16/2004	Mary Aldritt	208-022US1	8476

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ALLISON JOHNSON, P.A.
LAKE CALHOUN EXECUTIVE CENTER
3033 EXCELSIOR BLVD., SUITE 467
MINNEAPOLIS, MN 55416

EXAMINER	
HOFFMAN, SUSAN COE	

ART UNIT	PAPER NUMBER
1655	

NOTIFICATION DATE	DELIVERY MODE
07/10/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patent@ajiplaw.com
allison@ajiplaw.com

Office Action Summary	Application No.	Applicant(s)	
	10/759,892	ALDRITT ET AL.	
	Examiner	Art Unit	
	Susan Coe Hoffman	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 March 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,18 and 20-34* is/are pending in the application.

4a) Of the above claim(s) *20-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-16,18 and 31-34* is/are rejected.

7)☒ Claim(s) *2* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed March 13, 2009 has been received and entered. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior Office action. The declaration of Kyle Johnson, filed March 13, 2009, has been considered.

2. Claims 32-34 have been added in this amendment.

3. Claims 1-16, 18 and 20-34 are pending.

4. In the reply filed on July 11, 2006, applicant elected Group I, now claims 1-16, 18 and 31-34, without traverse.

5. Claim 20-30 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on July 11, 2006.

6. Claims 1-16, 18 and 31-34 are examined on the merits.

Claim Rejections - 35 USC § 103

7. Claims 1, 3-5, 8-10, 13, 15, 18, and 31-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brennan (AU 200157788) in view of Lieberman et al. eds. (*Pharmaceutical Dosage Forms: Tablets*. Second Edition, volume 1. New York: Marcel Dekker, Inc. 1989. pp. 285-303).

Brennan teaches an effervescent tablet which contains cranberry extract. The cranberry extract used in formulating the tablet is a water soluble powdered concentrate from cranberry juice (see page 8, lines 22-end). Brennan does not state that this concentrate contains proanthocyanidins. However, Hynes (US 2002/0192350) shows that proanthocyanidins are

naturally present in cranberry juice. Thus, the cranberry juice concentrate used in Brennan would also contain proanthocyanidins.

Brennan teaches an example of the effervescent tablet which contains citric acid, sodium bicarbonate, 200 mg of cranberry extract, 1451 mg of lactose, sucralose, blackcurrant flavor and polyethylene glycol to form a 4000 mg tablet (see Example spanning pages 12 and 13). Page 8 of applicant's specification defines lactose as a binder and polyethylene glycol as a lubricant. The reference example contains 5% cranberry (200 mg / 4000 mg) and 36% binder (1451 mg/ 4000 mg). The reference also suggests using 500 mg of the active, natural, therapeutic substance (see page 8, line 17). Following this suggestion would lead an artisan to formulate a tablet with 500 mg of cranberry extract. The total tablet would then weigh 4300 mg and would have 11% cranberry extract (500 mg / 4300 mg). The reference teaches that the cranberry composition is active against Escherichia coli and urinary tract infections (see page 10).

Brennan does not specifically teach formulating the tablet so that is dissolves in less than 2.5 minutes to form a solution free of granules, particles, and surface scum and does not teach formulating the tablet so that it has the hardness claimed by applicant.

Lieberman teaches making effervescent tablets using effervescent acids and bases, binders, lubricants and flavoring agents. Lieberman teaches using sodium benzoate in the tablets as well as sodium bicarbonate, citric acid and polyethylene glycol (see pages 287-292, 294). The reference teaches that it is important to formulate a tablet that dissolves completely and quickly, specifically in less than two minutes (see pages 287 and 302). The reference also teaches that it is important to formulate the tablet in a manner that does not result in picking, capping, die wall etching and lamination of the tablet (see page 299). Lieberman teaches that

modifying the hardness and amount of binder used improves the physical characteristics of the tablet and reduces picking, capping, die wall etching and lamination (see page 299). Lieberman also teaches that it is important to optimize the hardness of the tablet because the hardness is related to the amount of time it takes for the tablet to dissolve (see page 302). "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, it would have been obvious for an artisan of ordinary skill to modify the hardness of the tablet and the amount of binder used in the tablet because Lieberman teaches these are conditions that can be varied in order to produce the optimal tablet. Therefore, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

8. Claims 5-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brennan and Lieberman as applied to claims 1, 3-5, 8-10, 13, 15, 18, and 31-34 above, and further in view of Usukura (JP 2001-342142 - translation provided).

As discussed above, Brennan and Lieberman teach an effervescent tablet which contains cranberry extract as the active pharmaceutical ingredient. Brennan teaches that the cranberry in the tablet is useful for treating urinary tract infections (see page 10). Brennan teaches a specific example which uses 200 mg of cranberry extract. Brennan also states that the active ingredients can be included in amounts of 500 mg or more (see page 8, lines 15-19); however, it does not specifically teach using higher amounts of cranberry extract.

Usukura teaches using cranberry extract to treat urinary tract infections. The reference teaches that dosages between 100 to 5000 mg are useful dosages (see paragraphs 11 and 12).

Thus, an artisan of ordinary skill would reasonably expect that these dosages of cranberry extract would be useful in the effervescent tablet taught by Brennan and Lieberman to treat urinary tract infections. Based on this reasonable expectation of successful results, an artisan of ordinary skill would have been motivated to modify the tablet taught by Brennan and Lieberman to include cranberry amounts within the dosages taught by Usukura. Thus, the combination of the references properly teaches the stated claims.

9. Claims 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brennan and Lieberman as applied to claims 1, 3-5, 8-10, 13, 15, 18, and 31-34 above, and further in view of Korab (US 4,704,269).

As discussed above, Brennan and Lieberman teach an effervescent tablet which contains citric acid, sodium bicarbonate, cranberry extract, polyethylene glycol, and sodium benzoate. The references do not specifically teach including sorbitol in the tablet.

Korab teaches that using 15 to 25% of sorbitol while making effervescent compositions was conventional and known in the art at the time of the invention (see column 5, lines 60-end). Thus, an artisan of ordinary skill would have reasonably expected that this conventional ingredient could be used successfully in the tablet taught by Brennan and Lieberman. This reasonable expectation of success would have motivated the artisan to modify the tablet of Brennan and Lieberman to include sorbitol.

10. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brennan and Lieberman as applied to claims 1, 3-5, 8-10, 13, 15, 18, and 31-34 above, and further in view of Mann (US 2002/0102336).

The teachings of Brennan and Lieberman are discussed above. Brennan teaches using cranberry powder mixed with a carrier prior to use in the effervescent tablet (see page 8, lines 22-25) but does not specifically teach using magnesium hydroxide.

Mann teaches using a liquid solution comprising magnesium hydroxide to stabilize cranberry extract. The liquid solution and the cranberry extract are mixed and then dried to form a stable cranberry extract powder (see paragraph 15). Thus, an artisan of ordinary skill would have reasonably expected that the stability of the cranberry extract powder used in Brennan could have been improved if it was processed with magnesium hydroxide as taught by Mann. This reasonable expectation of success would have motivated the artisan to modify the tablet taught by Brennan and Lieberman to include magnesium hydroxide.

11. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nawar (US 6,641,847) in view of Lieberman et al. eds. (*Pharmaceutical Dosage Forms: Tablets*. Second Edition, volume 1. New York: Marcel Dekker, Inc. 1989. pp. 285-303) and any one of Takaichi (US 5,919,483), Alexander (US 4,783,331) or Schmitt (US 3,653,914).

Nawar teaches pharmaceutical compositions which comprise cranberry seed oil. The reference teaches formulating the composition into oral dosage forms that contains 1 to 1000 mg of the cranberry seed oil (see column 8, lines 55-59 and column 19, lines 28-40). The reference does not specifically teach formulating the composition into an effervescent tablet.

Lieberman teaches making effervescent tablets using effervescent acids and bases, binders, lubricants and flavoring agents (see pages 287-292, 294). The reference also discusses how to create an effervescent tablet that contains oil (see page 298). The reference teaches that it is important to formulate a tablet that dissolves completely and quickly, specifically in less than

two minutes (see pages 287 and 302). The reference also teaches that it is important to formulate the tablet in a manner that does not result in picking, capping, die wall etching and lamination of the tablet (see page 299).

The reference teaches that effervescent tablets are superior dosage forms because they are convenient, easy-to-use, premeasured and can be individually packaged to avoid product instability. The reference also teaches that formulating pharmaceuticals into effervescent tablets increases the bioavailability of the pharmaceutical (see page 285 and 286). Thus, an artisan of ordinary skill would reasonably expect that the cranberry seed oil pharmaceutical composition taught by Nawar could be improved by formulating the composition into an effervescent tablet as taught by Lieberman. This reasonable expectation of success would motivate the artisan to modify Nawar to include formulating the cranberry seed oil into an effervescent tablet as taught by Lieberman.

Thus, Nawar and Lieberman taken together are considered to teach an effervescent tablet which contains cranberry seed oil. The references do not specifically teach that the tablets have the hardness claimed by applicant. However, Lieberman teaches that modifying the hardness improves the physical characteristics of the tablet and reduces picking, capping, die wall etching and lamination (see page 299). Lieberman also teaches that it is important to optimize the hardness of the tablet because the hardness is related to the amount of time it takes for the tablet to dissolve (see page 302). "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, it would have been obvious for an artisan of ordinary skill to modify the hardness of the tablet because Lieberman

teaches that this is a conditions that can be varied in order to produce the optimal tablet. Therefore, absent some demonstration of unexpected results from the claimed parameter, this optimization of degree of hardness would have been obvious at the time of applicant's invention.

In addition, Lieberman teaches that when oils are incorporated into effervescent tablets, the oils should be included in a concentration of 1% or less (see page 292). However, the reference does not teach specific milligram amounts of oils to use or specific total weights for the effervescent tablets. However, Takaichi, Alexander, and Schmitt each teach creating effervescent tablets that weight between 5,000 and 5,780 mg (see Table 1 of Takaichi; column 7, lines 8-10 of Alexander; and column 6, lines 48 and 64 and column 7, line 5 of Schmitt). Thus, it was known in the art at the time of invention that tablets between 5,000 and 5,780 mg were a functional size to utilize when creating an effervescent tablet. Therefore, an artisan of ordinary skill would have been motivated to use these sizes when creating the effervescent tablet taught by the combination of Nawar and Lieberman. This would lead an artisan to incorporate between 50 and 57.8 mg of cranberry seed oil (i.e. 1% of 5,000 to 5,780 mg) into the tablet due to the teaching of Lieberman of the incorporation of 1% of oils based on the total weight of the tablet. This reasonable expectation of success results would have motivated the artisan to create an effervescent tablet with parameters that meet the limitations of applicant's claim 16.

Conclusion

12. Claim 2 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

13. Claims 1, 3-16, 18 and 31-34 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe Hoffman whose telephone number is (571) 272-0963. The examiner can normally be reached on Monday-Thursday, 8:30-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Susan Coe Hoffman/
Primary Examiner, Art Unit 1655